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APPLICATION NO.	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/571,802	12/13/95	ISHII	D

18N2/0116

JANELLE D WAACK
ARNOLD WHITE AND DURKEE
P O BOX 4433
HOUSTON TX 77210-4433

EXAMINER	
PAK, M	
ART UNIT	PAPER NUMBER
1812	10

DATE MAILED: 01/16/98

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

a) ☐ is extended to run _____ or continues to run _____ from the date of the final rejection

b) ☒ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition , and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☐ Applicant's response to the final rejection, filed _____ has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☒ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:

   a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.

   b. ☒ They raise new issues that would require further consideration and/or search. (See Note).

   c. ☒ They raise the issue of new matter. (See Note).

   d. ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

   e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: 1.b. THE SCOPE OF CLAIMS 1-6, 8-13, 16-23 NOW ENCOMPASS PROPHYLACTIC TREATMENT OF DISEASE DUE TO THE TERM AMENDED TERM "PREVENT" WHICH WOULD REQUIRE FURTHER CONSIDERATION AND SEARCH. 1.c. THE APPLICANT DID NOT SPECIFICALLY PROVIDE SUPPORT FOR THE TERM "PREVENT". THE EXAMINER COULD NOT FIND SUPPORT FOR THE AMENDED TERM "PREVENT".

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing an appeal, the proposed amendment ☐ will be entered ☒ will not be entered and the status of the claims will be as follows:

   Claims allowed: none
   Claims objected to: none
   Claims rejected: 1-6, 8-13, 15-20

   However;

   ☐ Applicant's response has overcome the following rejection(s): _____

4. ☒ The ~~affidavit, exhibit or~~ request for reconsideration has been considered but does not overcome the rejection because SEE ATTACHMENT

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficent reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☒ Other Please note attachment to advisory for #4.

Stephen Walsh
SPE, AU 1812
S. WALSH

PTOL-303 (REV. 5-89)

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Attachment to Advisory Action

Double Patenting

1. Claims 1-2, 8-9, and 15-16 remains provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-9, 14-17, and 22-24 of copending Application No. 08/398,852. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons set forth in the last office action and set forth below.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant argues that a terminal discliamer to overcome this rejection will be submitted when the pending cliams are indicated as being in condition for allowance. However, until the terminal disclaimer has been entered the rejection will be maintained.

Claim Rejections - 35 USC § 112

2. Claims 1-4, 8-11, and 15-18 remains rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of parenteral administration of IGF-I, IGF-II, or a combination of both IGF-I and II for the treatment of locus ceruleus noradrenergic neurons ablation by 6-

hydroxydopamine, does not reasonably provide the full scope of enablement for parenteral administration of IGF-I or IGF-II, for effecting any changes in the biochemistry or function of the central nervous system (CNS) or spinal cord and treating any disorders or diseases in the brain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the reasons set forth in the last office action and set forth below.

Applicant argues that the references listed on pages 4-8 of the remarks section of the amendment disclose research results that demonstrate that the teachings of applicant's disclosure are enabling. However, Knusel et al., Liu et al., Bozycko et al., Cheng et al., Dore et al., and Mozelle et al. disclose in vitro cultures of different types of neurons treated with IGF-I or IGF-II which, as discussed in the last office action, does not provide the full scope of enablement of the invention because the references of Baringa (A34), Jackowski(R), and Shepherd(S) provide the state of the art before and after the time of the invention that treatments of nervous system diseases with neurotrophic factors are unpredictable and that treatment of any one disease is not predictive of another. Thus, if the in vivo treatment is not predictive of another in vivo treatment, the reference articles have not provided support that in vitro

treatment is predictive of in vivo treatment with IGF. Furthermore, Thornton et al. and Kitraki et al. references provided by the applicant disclose the measurement of IGF receptor level and measurements of IGF-II RNA in microscopic tissue sections which does not provide the full scope of enablement of the invention because as dicussed above the treatments of nervous system diseases with neurotrophic factors are unpredictable and that treatment of any one disease is not predictive of another. Thus, if the in vivo treatment is not predictive of another in vivo treatment, the reference articles have not provided support that in vitro experiments of IGF or IGF receptor level is predictive of in vivo treatment with IGF. The last set of references, Mooney et al., MacIntosh et al., Saatman et al., Hatton et al., disclose IGF-1 administration, but the applicant fails to provide the full scope of enablement because as dicussed above the treatments of nervous system diseases with neurotrophic factors are unpredictable and that treatment of any one disease is not predictive of another. Furthermore, many of the references were published post-filing date and the applicant failed to disclose how the measurements of the different references were taught by the specification to enable the invention.

3. Claims 1-4, 8-11, and 19-20 remains rejected under 35 U.S.C.

112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the last office action.

Applicant argues that the amendment overcomes the rejection, however, the amendment has not been entered.

Claim Rejections - 35 USC § 102

4. Claims 1-6, 8-13, and 15-18 remains rejected under 35 U.S.C. 102(e) as being anticipated by Lewis et al.(A1) for the reasons set forth in the last office action and set forth below.

Applicant argues that the examiner has not established a case of enablement. However, the patent is presumed enabled by the examiner without evidence to the contrary.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Pak whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Walsh, can be reached on (703) 308-2957. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and

should be addressed to [**stephen.walsh@uspto.gov**].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MDP
Michael D. Pak
1812
13 January 1998

Stephen Walsh
S. WALSH
SPE AU 1812